4128. Adulteration and misbranding of Carbolatum salve. U. S. v. 193 Jars, etc. (F. D. C. No. 34612 Sample Nos. 3020-L, 3021-L.)

LIBEL FILED: January 26, 1953, District of Columbia.

ALLEGED SHIPMENT: On or about June 11, July 23, and August 11, 1952, by the Windsor Chemical Laboratories, from Philadelphia, Pa.

PRODUCT: 193 4-ounce jars and 165 14-ounce jars of *Carbolatum salve* at Washington, D. C. Analysis showed that the product in the 4-ounce jars contained not more than 1.55 percent of phenol and that the article in the 14-ounce jars contained not more than 0.67 percent of phenol. The National Formulary specifies that carbolic acid ointment contains not less than 1.8 percent of phenol.

LABEL, IN PART: (Jar) "Fleming's Carbolatum Salve for Man and Beast * * * Instructions: Carefully sooth injured member with warm water and apply Carbolatum twice a day as required. * * * For skin irritation mix one part Sulphur with four parts Carbolatum and use daily."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Carbolic Acid Ointment," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained a smaller proportion of phenol than the minimum specified in the National Formulary.

Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not an effective treatment for such conditions: "Carbolatum * * * soothes skin surface pains. For skin irritation mix one part Sulphur with four parts Carbolatum and use daily. For The Family A Great aid for * * * Bruises * * * and Irritated Skin * * * For Animals Skin Eruptions * * * Cow Pox." Further misbranding, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe dosage and methods of application, in such manner and form, as are necessary for the protection of users since it contained phenol; and the labeling of the article failed to bear a warning against application to large areas of the body or against its use under a bandage on fingers or toes.

DISPOSITION: June 2, 1953. Default decree of condemnation. The court ordered that the product be delivered to a local hospital for its use and not for sale. The product was to be used in the maintenance department of the hospital, for machinery lubrication.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4129. Adulteration and misbranding of Cal-D-Fer tablets and tablets of mannitol hexanitrate with phenobarbital and adulteration of triple sulfa tablets. U. S. v. Shaw Pharmacal Co. Plea of guilty. Fine, $800. (F. D. C. No. 33766. Sample Nos. 11202-L, 12527-L, 31191-L.)

INFORMATION FILED: March 19, 1953, Eastern District of Missouri, against the Shaw Pharmacal Co., a corporation, St. Louis, Mo.

*See also No. 4128.